K083166

5 510(k) Summary

JAN 13 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I. General Information

Establishment

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern. PA 19355

Registration Number

2240869

Manufacturer

Siemens Mindit Magnetic Resonance Ltd.

Siemens MRI Center,
Gaoxin C. Ave. 2nd
Hi-Tech Industrial Park,
ShenZhen 518057, PR. China

Registration Number

3004754211

Contact

Elizabeth Lazaro
Technical Specialist. Regulatory Submissions
51 Valley Stream Parkway
Malvern. PA 19355
Phone: (610)448-3393
Fax: (610) 448-1787
e-mail:Elizabeth.lazaro@siemens.com

Device Name

Trade Name:	Speciality Coils for MAGNETOM ESSENZA
Classification Name:	Coil, Magnetic Resonance Speciality
Device Class:	Class II 21 CFR § 892.1000
Product Code:	MOS
Classification Panel:	Radiology

Performance Standards

None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

Intended Use

The Speciality Coils are indicated for use in conjunction with the 1.5T MAGNETOM ESSENZA, a magnetic resonance diagnostic devices (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, and that display the internal structure and/or function of the body. These images when interpreted by a trained physician yield information that may assist in diagnosis.

Device Description

The Speciality Coils are intended to be used in conjunction with the MAGNETOM ESSENZA, a Magnetic Resonance Diagnostic Device. These coils will be used to present images which reflect the spatial distribution and the other physical parameters derived from the images may also be produced.

The Speciality Coils will include: 8-Channel Wrist Coil, 4-Channel Special-Purpose Coil, 8-Channel Foot-Ankle Coil, and the Focus Shoulder Array Coil, Small for the existing 1.5T MAGNETOM ESSENZA Magnetic Resonance System.

Substantial Equivalence

Siemens believes that, within the meaning of the Safe Medical Device Act of 1990, the MAGNETOM ESSENZA with Speciality Coils are substantially equivalent to the following cleared medical devices:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens MAGNETOM Avanto 1.5 T (8-Channel Wrist Coil , 8-Channel Foot-Ankle Coil)	K032428	Oct 16, 2003
Siemens MAGNETOM ESSENZA 1.5 T (Focus Shoulder Array Coil)	K071925	Aug 14, 2007
MACHNET CAROTIDS COIL ARRAY ASSEMBLY	K012491	Oct 24, 2001

General Safety and Effectiveness Concerns:

The following safety and performance parameters:

[Safety]
-Maximum Static Field
-Rate of Change of Magnetic Field
-RF Power Deposition
-Acoustic Noise Level

[Performance]
-Geometric Distortion
-Slice Profile, Thickness and Gap
-High Contrast Spatial Resolution

Specified by the FDA Guidance document for MR Diagnostic Devices are unaffected by the modifications described within this notification.

The following parameters were considered for the new Speciality Coils:

[Safety]
-Biocompatibility

[Performance]
-Signal to Noise Ratio
-Image Uniformity

No new materials were used for the new speciality coils compared to their predicate device. Therefore no new biocompatibility tests were performed. Signal to Noise Ratio (SNR) and image uniformity tests were performed for the new speciality coils and the results presented in this submission show that they are equivalent with the predicate devices.

Conclusion as to Substantial Equivalence

Laboratory testing was performed to support this claim of substantial equivalence and to show that the technological differences do not raise any new questions pertaining to effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2009

Ms. Elizabeth Lazaro
Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
MALVERN PA 19533

Re: K083166
Trade/Device Name: Speciality Coils for MAGNETOM ESSENZA
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: September 23, 2008
Received: September 27, 2008

Dear Ms. Lazaro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known) K083166

Device Name: **Speciality Coils for MAGNETOM ESSENZA**

Indications for Use:

The speciality coils are indicated for use in conjunction with the 1.5T MAGNETOM ESSENZA, a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, and that displays the internal structure and/or function of the body.

These images when interpreted by a trained physician yield information that may assist in diagnosis.

.

(please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use____

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083166